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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,715	03/08/2002	Steven J. Catani	15117.0091	7318

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,715	CATANI ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7-10 and 12-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 7-10 and 12-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

The amendment filed 6/24/2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-4, 6, 11, and 49-54 have been canceled.

2. Claims 5, 7-9 have been amended.

3. Remarks drawn to rejections under 35 USC 102.

Claims 5, 7-10 and 12-48 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The allowability of claims indicated in the previous office action has been withdrawn and the following rejections are made of record.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code at paragraph 0042 on page 12 of the specification. See MPEP § 608.01.

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5,7-10 and 12-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al (US 5,498,709).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 7-10 and 12-36 are drawn to removal of impurities, including tetrachlorosucrose from a composition including sucralose and first and second impurities with first and second solvents having partial immiscibility, wherein the second solvent could be ethyl acetate and specific ratios of solvents and recovering sucralose via crystallization.

Navia et al teach the extraction of sucralose in an aqueous-brine solvent (first solvent) with impurities and extracting it with ethyl acetate (second solvent) to transfer impurities into the second solvent and then back-extract the ethyl acetate extracts with water (third solvent) to transfer the sucralose in to the water and retaining the second impurities in the first solvent (col. 9, line 54 through 10, lines 15-25; col. 6, lines 35-67). The sucralose is finally recovered by crystallization (col. 6, line 67).

Even though Navia et al may not teach exactly what is transferred from one phase into another, one of ordinary skill in the art knows that in such liquid-liquid extractions there is no complete transfer of any given component from one phase to another. Hence it would have been obvious to one of ordinary skill in the art at the time the invention was made to use solvents of different polarity in a method of extraction as instantly claimed since the basic extraction steps and the type of solvents used is seen to be taught in the prior art. It is well within the purview of one of ordinary skill in the art to manipulate the order of the extraction steps, the solvents and the ratios of the solvents used in the process for the purpose of optimization. This also applies to the method of claims 33-36 wherein sucralose is separated from other chlorinated derivatives since Navia's process uses chlorination of sucralose using a chlorinating agent and by applicants' admission in the specification (page 1, paragraph 002) such a chlorination process yields other chlorinated derivatives in addition to sucralose. Hence, the extraction process of Navia also includes the separation of chlorinated derivatives from sucralose.

One of ordinary skill in the art will be motivated do so since Navia's process which uses three solvents including a partially miscible solvent in the extraction process gives a fairly high purity level of sucralose (>91%, col. 10, lines 24). Navia also suggests the recycling of mother

liquors. Hence extracting the starting composition or the partly purified composition in a method as instantly claimed would improve the purity level even higher.

Claims 37-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke (AIC Book and Paper Group Annual, vol. 3, 1984, 13-58) in combination with Navia et al (US 5,498,709).

Independent claims 37 and 43 are drawn to a method removing impurities from a composition comprising sucralose and impurities via liquid extraction using solvents with different Hildebrand parameters, with dependent claims 38-42 and 44-48 reciting limitations with respect to solvent ratio, crystallization and the type of extraction process.

Burke presents a table of various solvents with their respective Hildebrand parameters (Table 1, Part 2, pages 2-5) and also teach that materials that are soluble in a particular solvent will also dissolve in a neighboring solvent, or in other words, a material will dissolve in two different solvents if their Hildebrand parameters are close and will not dissolve in two different solvents if the difference on the numerical value of their Hildebrand parameters is large (page 5, see under "Solvent Spectrum"). From the table it can also be seen that ethyl acetate and water have Hildebrand parameters of 9.1 and 23.5 respectively. Hence from the teaching of Burke any material that dissolves in ethyl acetate will not dissolve in water when both solvents are present in a mixture. This suggests that when a compound is present in a solvent along with impurities either the compound or the impurities can selectively be extracted using a second solvent with a different Hildebrand parameter.

The extraction process of Navia et al as discussed above demonstrates the separation of sucralose via extraction using water and ethyl acetate. These two solvents have different Hildebrand parameters whose numerical difference is large.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use solvents of different solubility parameters in a method for removing impurities from a composition comprising sucralose and impurities as instantly claimed since such a concept and a method is see to be taught in the prior art. It is well within the purview of one of ordinary skill in the art to choose the solvent pair, their ratios and order of extraction and other process parameters based on the teachings in the prior art in order to optimize the process.

One of ordinary skill in the art would be motivated to do so since Navia's process, which is seen to employ solvents with different Hildebrand parameters, gives sucralose with very high purity level.

Conclusion

Claims 5, 7-10 and 12-48 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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